Food and Drug Administration Webinar on Single Window Progress
Questions and Answers
March 24, 2015
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What is the status of the PGA MOUs who have the hold authority or admissibility authority? (I do not need names but rather just a general feel – are they all signed or 50/50?)

Elizabeth McQueen: So I did not study for this question and I cannot tell you the exact -- every last one but the vast majority of our MOUs have been signed and are in place and we are actively working the few remaining ones that are out there. As Domenic said, the FDA one is completed and just awaiting signatures. I believe that there may only be one more with old authority that is not finalized. But they are all of the signature process. 80-90% are signed, right? Yes, about 90%? Right. In a couple of cases, there is some information and an appendix that we want to be absolutely sure cannot be misconstrued so really nothing is in the way of holding that up there.

The PGA message set document contains additional FDA affirmation of compliance code for medical devices. For example, lot number, lot production, and start and end date. Will there be an opportunity for the trade community to provide comment on this additional element prior to November?

Captain Domenic Veneziano: Thank you for the question. The data elements are still being looked at, so they are in the process of getting the supplemental guidelines down and there was opportunity to identify what data elements are needed for admissibility purposes only. Those data elements are being currently reviewed and they will be looked at in terms of what is actually required, simply for the admissibility aspect of it so, for instance, something like a lot number for production can be followed up after the admissibility process or can be followed up during an inspection of a facility that might be an optional field so it will not be a mandatory field as part of a requirement. So we are going through that supplemental guide for all data elements associated with all FDA regulated commodities and we will be ironing them out to only those that are required for admissibility purposes. So, again, consider the document that is out there right now and that is being discussed a draft as we go through and whittle them down to only data elements that is going to be required for admissibility purposes only.

What is the underlying computer platform for ACE?

Maria Luisa Boyce: I do appreciate the question, but we did not invite an IT person to today's webinar and I can tell you that we're using an agile approach to ACE. That is as technical as I'm going to get on that one, but we will be more than happy to send you more information. By the way, let me make a commercial announcement that I think Elizabeth and Domenic mentioned: we are having a software vendor conference this Friday, March 27, and so that will be a great opportunity. If you are interested in finding out that information, please go to the CBP.gov webpage and you can find information on it, but we will send you that information and figure out how we can email that to the group. We will email you the information for the software vendor conference where we are discussing more in detail the information.

What will happen to the marked ITAC (Import Trade Auxiliary Communications System) Systems for FDA?

Captain Domenic Veneziano: So currently, ITACs is up and running and we are making some improvements to ITACs. As many of you know, it gives you the availability and provides you the capability of telling FDA when things are available for sampling. It also provides the ability to submit documents electronically to us and it provides you the ability to know the status of any entry by going in with the entry number. It is also going to be improved so that you can actually go in and take a look at the FDA notice of actions electronically if you wish to and to print them out. So it will not be going away immediately and it will probably be there for other purposes. When the document imaging system gets completed, we hope that it will be a seamless transition from DIS into ITACs for FDA so the capability will be through the cloud, per se, where you submit it in one location which would be DIS and it would go to all agencies through a signal window concept, but it would still come into FDA through ITACs into our system and be linked directly into the line entry. So it still is not going away. It is hopefully going to still be enhanced right now and then, as the document imaging system comes on play, we will figure out what it means in terms of ITACs in its current state.

Will standalone the Bioterrorism Act (BTA) be part of ACE?

Captain Domenic Veneziano: The Bioterrorism Act, as you all know, is the prior notice requirements which is still part of the import process for FDA in terms of admissibility. It is the first aspect of food coming into the United States, to ensure that those requirements are satisfied before it moves into the admissibility part. That will not change. It will be incorporated into ACE so it will still be the same process as we currently have -- however it will not be through ACS but it will be through the ACE environment.

The deadline for brokers to file ACE is November 1, 2015. What day will everything be online for brokers to be able to file?

Elizabeth McQueen: So part of the reason why, as Domenic mentioned, we will be ready to do the pilot for FDA on July 1, 2015, is that it is in the July deployment when we will have everything that we are building for that November deadline out. So actually, there are quite a few Partner Government Agencies whose pilots will begin in July and it is going to be very much like the starting gun of the horse race, even though we have had a few around the tracks a couple of times so the thought is that, in the very early part of the pilots, hopefully within certainly the first month, we will have a very good feel for the extent to which some slight changes might need to be done and still leave our software vendors out in the private space several months to get their coding completed in time for everyone to be able to meet the mandatory day.

How will the Single Window system affect the import/export of investigational drug products especially those consigned to investigational sites covered under an existing IND?

Captain Domenic Veneziano: We hope that it is going to be more efficient. Currently, as many of you know, during an investigational drug product, you have to provide a number for the agency to actually verify that it is under an investigational drug. During the process, if that information

is provided at the time of entry under the new PGA message set, then hopefully the system itself will verify all of that data electronically and release it in a much quicker time period and prevent the delays that currently happen in terms of human intervention of verification of that information. So that is where it is going. In terms of export, obviously, there is not much that we do for FDA wise in terms of the exportation of drugs or raw commodities.

Please advise, what does the acronym FACA stand for?

Maria Luisa Boyce: That would be Federal Advisory Committee Act. That is what FACA stands for.

Are ITACs still going to be in place and will entering in information remain the same?

Maria Luisa Boyce: I think that the Captain Veneziano already addressed that in his previous response. Next question:

How will the foreign supplier verification system undated by FISMA be implemented through this system?

Captain Domenic Veneziano: So they are two new regulations that are coming down the road. Obviously the Food Safety Modernization Act is one, and the FDA Safety and Innovative Act is the second that is being worked on. With each of those, we have already identified placeholders for the data elements that are going to be required when the rule gets issued. So we are aware that there will be some additional data elements that might be required because of the new legislation. The MOUs that have been signed address that so we are aware of it and they will be incorporated into the data – or the PGA message set - when all of the rules are finalized and we can make decisions on what is needed. Again, one thing that I will say, to piggy-back off of my last answer related to data elements and the affirmation of compliance, we are looking at what is required at the time of entry to make admissibility decisions in what is needed for the law and regulations that we enforce. So we are going to be prudent on what is required under FISMA and what is required to make it available for filers and manufacturers to get the information and quickly so that we can turn it around.

What about medical devices?

Maria Luisa Boyce: Could you please be more specific about what which medical devices you would like to know more about? Thank you and we will be happy to answer the question then.

How do we volunteer to be a test volunteer?

Elizabeth McQueen: The simplest way is to go to the website ITDS.gov and there is, in the red menu, a button called ITDS Pilot Programs and if you click on that button, you will actually get instructions for how you can express your interest in participating in the pilot and that is across the board for all of the pilots that we have. Also, if you happen to be a subscriber to the CSMS messaging service, we do put out CSMS messages when we are going to engage in a pilot requesting volunteers for the pilot.

Maria Luisa Boyce: Thank you so much, Elizabeth. I think that when we send the email to all of today's attendees, we will send a direct link to that so that everybody can have it and do that. The next question:

If you would like to be a part of the pilots, as a volunteer or tester, can you select what entries to do this with?

Elizabeth McQueen: That is actually a very good question. When we engage in a pilot, we specifically do a very finite small scale testing effort so that we can be absolutely certain of what we are looking at. So we do not open the floodgates and engage in that at every single port through every single mode of transportation for every single commodity. What we do is choose a subset of commodities that we are going to be looking at and we choose the subset of the ports that they are going to come in, and even as the case may be depending on the PGA, a subset of modes so the folks who will be participating in the pilot will be well aware of what specific items that we will be testing. So we do that limited and controlled small scale effort and then we expand that. So we might add commodities or we might go with the same commodities, but add more ports or add more minutes of transportation so that we can throw that in a controlled fashion and be sure that we do not have any surprises as we expand.

With DIS in effect, will ITACs be obsolete?

Captain Domenic Veneziano: I do not think so, but I think ITACs is a great tool for the industry and the industry likes it. It is a way for them to know the status of any entry very quickly. We also are making changes to that so you will have an idea of laboratory statuses as well which might not be available through ACE directly. Obviously, what we would love to do, is to have everything go to the filers as much as possible through ACE. So, the future is to kind of identify what kind of tests we are sampling and have that be something for our notices.

And the long-term goal would be that, in the FDA notice of actions that we issue, we would be specific in identifying what is being sampled for, and what it is being laboratory tested and being issued through ACE. I think that that is going to be a long-term goal so in the interim, I do not think that ITACs will be obsolete in its entirety. But we have to figure out how it is going to be utilized down the road.

When will FDA implementation guidelines for use of PGA message set be published in the CUTAIR?

Elizabeth McQueen: Currently the working group is reviewing that guidance and as I showed when I put the graphic of the process up on the screen, we go through that process of the working group thoroughly reviewing the IG so that we can do any iterative and recursive work on tweaking those before we put them up – generally, that is the preference.

That said, there is a place now in the CUTAIR where we have, separately, a group of chapters for PGAs who have already gone through that and a group for where they are draft and so, they are put up there for future use. We should have put the FDA one up on the site for future use and

I believe that it may be there now. […] Yes. It is there, under "supporting documentation" for future use under PGA message set.

When will the webinar be available online for others to view?

Maria Luisa Boyce: Within 48 hours, the webinar will be available for you to forward and send around. Please do so that a lot of people can listen and have the information. Next question.

I have heard that FDA's proposed message set includes a lot of new data elements that are not currently provided, including lot numbers and production, start and end dates. Are those still included and if so isn't that contrary to the Executive Order or have they been dropped?

Captain Domenic Veneziano: They will be addressed so most likely, they will not be mandatory but they will be optional as I mentioned earlier we are going to all of the data elements to make sure that only those that are required for admissibility purposes will be covered under the data element requirements.

Will there be a need for a Federal Register Notice for the FDA pilot? If so, when can we expect to see these?

Elizabeth McQueen: I think we are doing a combined one. Yes. It is actually going to be under CBP.

Captain Domenic Veneziano: And we are in the process of reviewing that document, the Federal Register Notice, and it will be again under CBP but it will include specifically what the pilot will look like, probably contain links to ports because the pilot is going to be probably run from July through November and, as was mentioned earlier, we want to start small and ramp up so as the ports come online, we want to have a link as to how we are going to roll it out and that is what we are in the process of doing so it should come out, I would imagine, I think it is within maybe the next month or so but it is coming through a review process right now.

Elizabeth McQueen: Worst-case scenario, the FRNs are put out 30 days prior to a pilot starting so it will be before then. So we will say, May, probably or April/May.

We have heard you (Captain Veneziano) speak before about FDA moving towards a more risk-based process versus treating all FDA regulated parts the same. Has there been improvement in this area and will ACE/ITDS help in this effort?

Captain Domenic Veneziano: I think it will help the process in terms of, I think we will be able to release on a line level, so what the future is going to deal with – let me back up a little. Currently, when we hold a line, that entire entry is held. So it prevents products from getting into commerce as quickly as they can. ACE/ITDS will change that and it will allow to release on a line level in the future and only allow FDA to hold those products that we really want to look at.

So we currently do have a risk-based system in place and, as many of you know, it is called PREDICT where it targets just based upon certain elements and based upon business rules so inherent risk of a product is weighed against each other to determine which ones have the highest need or have the highest risk to public health and we tie it against those. But ACE will improve the process and the work that we do, as well as working with other agencies together.

So if there is a concern from another agency or if FDA holds a product, that will be visible to other people who have jurisdiction over it. If we are holding something, you will have to do two exams, one for Customs maybe and then one for FDA. We will know at the same time that there is an interest of that shipment and it can kind of expedite the review process or the examination process of the shipment. It will help get products to the market a lot quicker. But we do already have a risk-based approach in terms of the work that we do so I hope that that answers the question.

Will this new process increase the efficiency of the import and release of fresh fruit and vegetable perishable shipments?

Captain Domenic Veneziano: I believe that it will. I believe that with the new ACE/ITDS implementation, I think the efficiencies will be quicker and I think there are a lot of aspects to that question and you have the Voluntary Qualified Importer Program, down the road, and the Border Interagency Executive Council Process and Risk Committee looking at trusted trade programs to help expedite shipments coming for us and recognizing who is C-TPAT and ISA certified. So I think that in the long run, looking at what the Executive Order is intended to do and the work that is going to be shared through ACE/ITDS, I think that will help expedite not only fruits and vegetables or food, but I think for all commodities that we regulate.

How will the PGA message set impact and/or work with PREDICT?

Captain Domenic Veneziano: Thank you for this question. This is pretty much the heart of why it is important for the PGA message set of the data elements to be submitted at the time of entry. PREDICT takes a look at the information that comes across and utilizes or searches other databases within FDA, if you will, to verify that the affirmation of compliance are accurate and efficient.

By providing them upfront, we are going to do a couple of things. First of all, CBP will be in the validation when it comes to them and they can validate that the data is in the right syntax, the number of characters are correct, and it will first screen it before it ever comes to FDA. It will provide you a warning just to let you know that this commodity needs a specific data element. Once it comes over to FDA, again, it will come in, it will go through PREDICT and it will go into our databases and verify that information and if everything is correct and the product is not a risk to FDA, or we do not have a concern over it, then it will be preceded by the system instantaneously. So you are talking about seconds versus days of a release if everything goes smoothly.

We are currently self-filing our customs entries in ACS. Do you anticipate any issue if we move to filing in ACE and are not part of the pilot? Do you foresee any complications that might arise if the FDA portion is not completely tested before the November 1, 2015 deadline?

Elizabeth McQueen: If I understand the question correctly, it sounds as though this person does not want to officially participate in the pilot but will still want to start filing in ACE?

So in the beginning, when we are just in the pilot phase, I do not believe that we are going to let just anybody and everybody file. They have to be a pilot participant. Yes, but we do encourage you, from a Customs perceptive, to file in ACE now and there is not going to be a problem on that part if you move to ACE.

Captain Domenic Veneziano: On the FDA side, let me address: do you see foresee any complications that might arise if the FDA portion is not completely tested before the November 1, 2015 deadline.

I can guarantee that it will be tested before that day. So we are working on that and to test if the system side of things – the ACE/ITDS working group and the technical people have worked hard at making sure the systems are working together and the pilot is going to start in July. That is going to verify that everything is working and we will turn it off quickly if we need be but between July and November, we are going to be testing and having metrics to determine what success is going to be and to make sure that it is working smoothly before we ever finish in November. There are a lot of conversations that have to happen in that time period and to monitor the success of the program so I can guarantee you that it will be tested to its fullest extent between July and November before ACS is turned off.

Maria Luisa Boyce: Yes, we are going to be doing a lot of outreach, not only through webinars like this, but also going to different ports of entry so that we can have outreach with the community to help facilitate that participation and testing.

Elizabeth McQueen: We are encouraging everybody to file in ACE – my apologies for the confusion.

Captain Domenic Veneziano: One of the big aspects of the pilots and I need to emphasize is the impact on industry. So yes, the systems have to be working for the agencies, but we also want there to be impact on the industry and focus on what changes have to be made and how it is working for you all in terms of submitting the entries and what difficulties you are having.

That is part of the BIEC role in terms of the rollout, to capture that and to get the input from the industry in terms of how it is affecting you as we transition from ACS to ACE.

How does the electronic interface address the USDA requirements for original documents for VS permits?

Maria Luisa Boyce: With that question, actually, I would have loved you to ask that in the webinar we had with APHIS but we will get back to you on that question. We are not able to answer that now but we will get back to and provide you the information. Next question.

Why does the FDA propose rulemaking to require those remaining voluntary items to achieve uniform filings for affirmation of compliance? Seems [Indiscernible – static] to have all of the information at the same time.

Captain Domenic Veneziano: We are going to put out a Federal Register Notice rulemaking and it can be a little bit more difficult in terms of the client. With 7-2-713 -- for FDASIA, where we have to make it a rulemaking in terms of requiring data element and for a product that is subject to review. So it is a little bit difficult in terms of the rulemaking process versus a Federal Register Notice so it is a lot quicker, I think, to go through a Federal Register Notice asking for these data elements to be submitted at the time of the entry so that we can accomplish the goal of expediting shipments in the long run and that is what our goal is to try to expedite as quickly as possible and to kind of let the systems do our work for us rather than the human interventions. With 34 million lines of shipments each year, we have to find a better way and a more efficient way to do our job and through the implementation of ACE/ITDS and the Executive Order, I think that we can get there.

When an FDA hold for documentation is requested in ACE after a Customs entry has been transmitted, will the documents be uploaded into ACE or will we still upload them on the MARCS website?

Captain Domenic Veneziano: Currently, they will still be uploaded into the MARCS website until DIS comes into play and then there will be procedures and we will be communicating how that will get done in the future.

What additional data elements are mandatory for November 1, 2015?

Captain Domenic Veneziano: That will be in the supplemental guide and we will be communicating on many aspects on this. We will have that on a website on what is required. We will also send out a CSMS Notice to the filer on all the requirements that are going to be changing. It will also be part of the Federal Register Notice when it gets issued.

When the Federal Register Notice goes out regarding the pilot in July, when does the request for volunteers for this pilot go out?

Elizabeth McQueen: They are really sort of one-in-the-same because we have to know what commodities are going to be part of that pilot before we can know who ought to be participating in the pilot. Anyone who is interested is certainly welcome to express their interest as early as possible and as soon as we know what commodities we are talking about, we can validate that it

makes sense for you to take part in the pilot at that point. But as soon as the FRN goes out which will hopefully be soon.

Has the FDA-PGA message set been finalized and will all data elements be mandatory?

Captain Domenic Veneziano: It is still a draft and we're still doing the review and we are in the process of going through each one of them.

Any anticipated changes to the ITACs functionality and availability plan?

Captain Domenic Veneziano: Yes and we are working on additional functionality for that.

Will ACE allow for port code changes for FDA regulated goods?

Captain Domenic Veneziano: Yes. So this is going to be a big change and one of the big issues we have had are one of the big concerns that the industry has said is they cannot make changes for port codes or for any mistakes that have been made and in order to make the change, they have to delete the entry or cancel the entry and then resubmit. The beauty, I think, of some of the new changes to the system is that you will have the capability of submitting an entry 60 days in advance and it is going to go to the validation process and we hope to notify you if there is an issue.

Between 60 days and, I want to say a lockout time period for the mode of transportation, you will have the capability of making edits all along that way and we are trying to make sure that you have the capability of getting information or warnings from both CBP early on with the submission of them and then from FDA up to that cutoff date. You can always make changes after that cutoff date but at some point, the agency has to consider the information that was submitted and make a final decision.

We are identifying when things are going to be locked out for the entry review process. So you will have the capability of making it. The port code is a little bit difficult because often times, it is kind of at the time of arrival to make a port change so you do not know your change in ports due to a traffic or accident or something in that aspect so we have been working with the CBP to identify that. When possible, that port change can be made. But when not possible, we will deal with it operationally and the only major concern that we have is if we have set something up for examination and we -- FDA -- will work on making sure that the port that it is going to, as long as you notify us of the change, we can look at it.

Again, with ACE, one of the beauties of it is that everybody will know across the country that we are looking at that entry. If you make an entry at another port, it should be flagged accordingly that we want it to be stopped or set for examination. So we are working at it operationally with the changes cannot be made because of last minute issues but you will have a capability from 60 days up until the time of a lock down to make any changes.

Elizabeth McQueen: Let me add one little piece to that. Just by attending our demonstrations of our software under development, I am aware about another piece of functionality that people

might be interested in which is if we have a serious scenario, before you gave the example of an accident or a hurricane, and you cannot come into Houston, there is a feature that has been built into ACE where all of those shipments that are on ships that we are going to go into that the port, can be redirected to another port without you having to redo the entry. So that is going to be a great thing and I do not remember what they called that...It is "diversion."

Will any advance drafts of the FDA FRNs be available for review?

Elizabeth McQueen: No. We cannot share that but you are welcome to provide comments once the FRN has been made available to the public.

What about samples or codes which are not approved in the U.S.?

Maria Luisa Boyce: If you could please maybe give us a little bit more context for the question, then we will be more than happy to address it.

What about medical devices?

Captain Domenic Veneziano: I apologize. I excluded them. So medical devices have similar things and there are requirements for device registration numbers, device listing numbers, as well. I apologize, but I will amend the slide and make sure that Steve incorporates it into what we currently need for admissibility today. I apologize for that.

What are the challenges in communicating recommendations back to CBP through the Single Window?

Maria Luisa Boyce: Are you referring to messages back and forth? Are you talking about when the agencies are sending a message back to you that some information is still needed? Are there challenges with that? Please let us know a little bit more context with that question.

It appears that FDA uses HTS as the guidance for flagging commodities. Will this list get updated?

Captain Domenic Veneziano: The answer is yes. We look at harmonized tariff schedules often so we go through them on a yearly basis but we continuously update them to make sure that anything that is FDA regulated gets hit with an FDA flag to make sure that it comes into our jurisdiction.

Are we able to have the ability to correct errors made with FDA, such as FDA code or MIDs at the time of entry once it has already been transmitted?

Captain Domenic Veneziano: As I mentioned, you will have a lot of time between the 60 days and the lock-out time that we are establishing to make changes if you have made mistakes.

Will local customs field agents be ready for the full, mandatory agency ACE-implementation by November 2015 for full cargo release process?

Maria Luisa Boyce: Yes, they will be and they are ready. We are doing the internal training. This is from a Customs perspective and we are working on the training. As everything gets more ready and we have more information, we are scheduling the local training with our offices and you may understand that this is a big effort that we are working on.

Maria Luisa Boyce: Thank you for the question.

It was mentioned that during the tabletop exercise there was some pain points identified. Have these been addressed? Will this be shared with the trade? Will further tabletop exercises be conducted that include trade participants and if so when might it occur?

Captain Domenic Veneziano: So the six pain points have been addressed, but they have not been addressed in their entirety. We have explored the timely access to import data and as I mentioned, one of the big successes is getting it the 60 days in advance and working through the process of how we maximize data. We are also in the process of implementing or I should say CBP is in the process of issuing ATS-GC which is the capability of other agencies that are co-located with CBP to look at manifest data or other data that usually the agencies do not get access to so we are in the process of doing that.

We do have solutions to some of the other things. The third one is the federal role of data quality and validation and we have addressed that as I mentioned and there will be a validation step by Customs and Border Protection when the entry gets first submitted to verify that the data elements and PGA message set for admissibility decisions are there and not left blank if needed so based upon the commodity if there is a requirement that has to be submitted or filled out, it can be done with the warning going back so that has been completed.

The other four are scheduled to move forward and we are trying to address them moving forward but they all have kind of potential solutions and we will be working through them between now and December 2016.

Maria Luisa Boyce: And as far as interaction with the industry, we will try to find a venue to be able to do it and at least post the information and if we can, facilitate the dialogue. We will look into that part and see how we can assist.

Captain Domenic Veneziano: I would say that one of the major things, and Maria Luisa can speak to this, but the work of the Advisory Committee on Commercial Operations (COAC) has been instrumental and the FACA committees have been instrumental in the work that we have done in identifying some of the pain points, on their behalf, that they have seen and bringing them to the forefront for the agencies to address. So that work will continue and I expect that you will and the COAC will continue to play a major role going forward.

Maria Luisa Boyce: I think that will be a good way to connect with industry and we are going to be posting all of this information online and that way you can also send your questions.

What is the status of the USDA-APHIS Lacey Act information?

Elizabeth McQueen: So for the APHIS-Lacey Act program, the working group has already gone through their supplemental guidance and that guidance has been uploaded to CBP.gov in the CUTAIR and the PGA message set chapter but it is under the supporting documentation for future use section. Only because APHIS has not internally finalized the approval of the implementation guidance but it is there.

On shipments that the importer pays by check, how is Customs going to handle that? Since ACE rejects these entries now.

Maria Luisa Boyce: That is a very good question and we are going to look into that it to send you an answer via email.

Will the DIS be done through the ACE portal? That is another technical question that we will get back to.

Elizabeth McQueen: I don't believe so. It will actually be appended to the electronic section.

Maria Luisa Boyce: I think that that is where we are going to stop at this moment because we are getting a lot of questions. Thank you so much for all of the participation and all of the questions. What we are going to do is post this information online and for some of the questions that we did not answer, we will make certain to write an answer and send you that information.

Are all the BIEC reports to the President or made in part to the public record?

Maria Luisa Boyce: As Domenic mentioned, we have the www.CBP.gov/BIEC webpage and we will be posting more information as it becomes available.